**ARC 4363C**

# PUBLIC HEALTH DEPARTMENT[641]

**Notice of Intended Action**

**Proposing rule making related to medical cannabidiol program and providing an opportunity for public comment**

The Public Health Department hereby proposes to amend Chapter 154, "Medical Cannabidiol Program," Iowa Administrative Code.

*Legal Authority for Rule Making*

This rule making is proposed under the authority provided in Iowa Code section 124E.11.

*State or Federal Law Implemented*

This rule making implements, in whole or in part, Iowa Code sections 124E.2, 124E.4 and 124E.11.

*Purpose and Summary*

The proposed amendments will implement needed updates to the rules to provide proper oversight of the program. These amendments are in response to issues that have become apparent since the program was initiated. Updates include:

- A mechanism to update the list of debilitating conditions when new conditions are approved by the Board of Medicine;
- Revisions to the definitions of "debilitating medical condition," "plant material" and "stability" and the addition of a definition of "owner";
- Prohibitions for health care practitioners, including self-certifying, advertising certification services, or accepting remuneration beyond a consultation fee for certifying conditions;
- A mechanism to allow patients and primary caregivers to cancel their registration cards;
- Simplification of labeling requirements for manufacturers and dispensaries; and
- Movement of laboratory testing requirements for manufacturers to the laboratory testing requirements and acceptance criteria document where the requirements can be updated as needed.

*Fiscal Impact*

This rule making has no fiscal impact to the State of Iowa.

*Jobs Impact*

After analysis and review of this rule making, no impact on jobs has been found.

*Waivers*

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department's variance and waiver provisions contained in 641—Chapter 178.

*Public Comment*

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on April 16, 2019. Comments should be directed to:

Randy Mayer
Department of Public Health
Lucas State Office Building
321 East 12th Street
Des Moines, Iowa 50319
Email: randall.mayer@idph.iowa.gov

*Public Hearing*

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)"b," an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

*Review by Administrative Rules Review Committee*

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Amend rule **641—154.1(124E)**, definitions of "Debilitating medical condition," "Plant material" and "Stability," as follows:

*"Debilitating medical condition"* means any of the following:

1. Cancer, if the underlying condition or treatment produces one or more of the following:
- Severe or chronic pain.
- Nausea or severe vomiting.
- Cachexia or severe wasting.

2. Multiple sclerosis with severe and persistent muscle spasms.
3. Seizures, including those characteristic of epilepsy.
4. AIDS or HIV as defined in Iowa Code section 141A.1.
5. Crohn's disease.
6. Amyotrophic lateral sclerosis.
7. Any terminal illness, with a probable life expectancy of under one year, if the illness or its treatment produces one or more of the following:
- Severe or chronic pain.
- Nausea or severe vomiting.
- Cachexia or severe wasting.

8. Parkinson's disease.
9. Untreatable pain.
10. Any medical condition that is recommended by the medical cannabidiol board and adopted by the board of medicine by rule pursuant to Iowa Code section 124E.5 and that is listed in 653—subrule 13.15(1).

*"Plant material"* means any cannabis plant, cutting, trimming, flower, or clone ~~that has roots or that is cultivated with the intention of growing roots~~ of *Cannabis sativa* L. or *Cannabis indica*.

*"Stability"* or *"stable"* means that after storage of an unopened package of medical cannabidiol at a licensed manufacturing facility or dispensary facility, the contents shall not vary in concentrations of THC and CBD by more ~~or less than 15 percent by weight in milligrams per milliliter (mg/ml) for liquids and milligrams per gram (mg/g) for solids from the concentration indicated on the package label~~ than an amount determined by the department and listed in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1). ~~Thus, after storage, a solid product labeled~~

~~as containing a concentration of CBD of 10 milligrams per gram shall have a detected concentration of CBD that is no more than 11.50 milligrams per gram and no less than 8.50 milligrams per gram.~~

ITEM 2. Adopt the following **new** definition of "Owner" in rule **641—154.1(124E)**:

*"Owner"* means a person with a 5 percent or greater ownership interest in a manufacturer or dispensary.

ITEM 3. Amend rule 641—154.2(124E), catchwords, as follows:

**641—154.2(124E) Health care practitioner certification—duties and prohibitions.**

ITEM 4. Adopt the following **new** subrule 154.2(4):

**154.2(4)** Health care practitioner prohibitions.

*a.* A health care practitioner shall not accept, solicit, or offer any form of remuneration from or to any individual, including but not limited to a patient, a primary caregiver, or an employee, financial backer, or principal of a medical cannabidiol manufacturer or dispensary, to certify a patient's condition, other than accepting a fee for a patient consultation to determine if the patient should be issued a certification of a qualifying debilitating medical condition.

*b.* A health care practitioner shall not accept, solicit, or offer any form of remuneration from or to any individual, including but not limited to a patient, a primary caregiver, or an employee, financial backer, or principal of a medical cannabidiol manufacturer or dispensary, to certify an individual as a primary caregiver for a patient with respect to the use of medical cannabidiol, other than accepting a fee for a consultation to determine if the individual is a necessary caretaker taking responsibility for managing the well-being of the patient with respect to the use of medical cannabidiol.

*c.* A health care practitioner shall not advertise certifying a qualifying debilitating medical condition as one of the health care practitioner's services.

*d.* A health care practitioner shall not certify a qualifying debilitating medical condition for a patient who is the health care practitioner or a family or household member of the health care practitioner.

*e.* A health care practitioner shall not be designated to act as a primary caregiver for a patient for whom the health care practitioner has certified a qualifying debilitating medical condition.

*f.* A health care practitioner shall not receive or provide medical cannabidiol product samples.

ITEM 5. Amend subrule 154.3(4) as follows:

**154.3(4)** Every patient 18 years of age or older must obtain a valid medical cannabidiol registration card to use medical cannabidiol in Iowa. The department may waive this requirement for a patient who is unable to obtain a card because of health, mobility, or other issues as long as the patient has designated a primary caregiver.

ITEM 6. Amend rule 641—154.6(124E) as follows:

**641—154.6(124E) Denial and cancellation.** The department may deny an application for a medical cannabidiol registration card, or may cancel or direct the department of transportation to cancel a medical cannabidiol registration card, for any of the following reasons:

1. Information contained in the application is illegible, incomplete, falsified, misleading, deceptive, or untrue.

2. The department or the department of transportation is unable to verify the identity of the applicant from the photo identification or other documentation presented pursuant to paragraph 154.3(1)*"d"*(2)"3" or 154.4(1)*"c"*(3)"4."

3. The applicant violates or fails to satisfy any of the provisions of Iowa Code chapter 124E or these rules.

4. A patient, the patient's legal guardian, or other person with durable power of attorney requests in writing that the department cancel the patient's medical cannabidiol registration card.

5. A primary caregiver requests in writing that the department cancel the primary caregiver's medical cannabidiol registration card.

6. The department becomes aware of the death of a patient or primary caregiver.

ITEM 7. Adopt the following **new** subrule 154.16(7):

**154.16(7)** *Recall of medical cannabidiol products.* The department may require a manufacturer to recall medical cannabidiol from dispensaries and patients when there is potential for serious health consequences from use of the products as determined by the department. Situations that may require a recall include but are not limited to:

*a.* The distribution, sale, or use of the medical cannabidiol creates or poses an immediate and serious threat to human life or health.

*b.* Other procedures available to the department to prevent or remedy a situation would result in an unreasonable delay that may place the health of patients at risk.

ITEM 8. Amend rule 641—154.17(124E) as follows:

**641—154.17(124E) Manufacturer operations.**

**154.17(1)** *Operating documents.* ~~The operating documents of a manufacturer shall include all of the following:~~

*a.* A manufacturer shall maintain operating documents that accurately reflect the manufacturer's standard operating procedures. Upon a request, a manufacturer shall make the operating documents available to the department through secure electronic mail, an electronic file-sharing service, or other secure means.

~~*a.*~~ *b.* The operating documents of a manufacturer shall include all of the following:

(1) Procedures for the oversight of the manufacturer, including descriptions of operational and management practices regarding:

~~(1)~~ 1. The forms and quantities of medical cannabidiol products that are produced at the manufacturing facility;

~~(2)~~ 2. The methods of planting, harvesting, drying, and storing cannabis;

~~(3)~~ 3. The estimated types and amounts of all crop inputs used in the production of medical cannabidiol;

~~(4)~~ 4. The estimated types and amounts of medical cannabidiol waste and plant material waste to be generated;

~~(5)~~ 5. The disposal methods for all waste materials;

~~(6)~~ 6. Employee training methods for the specific phases of production;

~~(7)~~ 7. Biosecurity measures and standard operating procedures used in the production and manufacturing of medical cannabidiol;

~~(8)~~ 8. Strategies for identifying and reconciling discrepancies in inventory of plant material or medical cannabidiol;

~~(9)~~ 9. Sampling strategy and quality testing for labeling purposes;

~~(10)~~ 10. Medical cannabidiol packaging and labeling procedures;

~~(11)~~ 11. Procedures for recall and market withdrawal of medical cannabidiol;

~~(12)~~ 12. Plans for responding to a security breach at a manufacturing facility or while medical cannabidiol is in transit to a dispensary;

~~(13)~~ 13. A business continuity plan;

~~(14)~~ 14. Records relating to all transport activities; and

~~(15)~~ 15. Other information requested by the department.

~~*b.*~~ (2) Procedures to ensure accurate record keeping.

~~*c.*~~ (3) Procedures for the implementation of appropriate security measures to deter and prevent the theft of medical cannabidiol and unauthorized entrance into areas containing medical cannabidiol.

*c.* Operating documents may be trade secrets if designated as such by a manufacturer and shall be considered confidential records pursuant to Iowa Code section 22.7(3).

**154.17(2)** No change.

**154.17(3)** *Criminal background investigations.*

*a.* A manufacturer shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history record check.

*b.* An employee of a manufacturer shall not have been convicted of a disqualifying felony offense and shall be subject to a background investigation conducted by the department of public safety, including but not limited to a national criminal history background check.

*c.* An applicant or licensed manufacturer shall respond within 30 days to a request from the department or the department of public safety for more information to complete a background investigation and national criminal history background check on an owner, investor, or employee.

**154.17(4)** No change.

ITEM 9. Amend subrule 154.21(3) as follows:

**154.21(3)** *Package labeling.*

*a.* A manufacturer shall ensure that all medical cannabidiol packaging is labeled with the following information:

(1) The name ~~and address~~ of the manufacturer ~~where the medical cannabidiol was manufactured~~;

(2) The medical cannabidiol's primary active ingredients, including concentrations of tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid. Concentrations of tetrahydrocannabinolic acid and cannabidiolic acid may be omitted if the manufacturer uses chemical decarboxylation or other means to substantially remove the acids from the product prior to testing;

~~(3) Directions for use of the product, including recommended and maximum amount by age and weight, if applicable;~~

~~(4)~~ (3) All ingredients of the product shown with common or usual names, including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight;

~~(5)~~ (4) Instructions for storage, including light and temperature requirements, if any;

~~(6)~~ (5) Product expiration date;

~~(7)~~ (6) The date of manufacture and lot number;

~~(8)~~ (7) A notice with the statement, including capitalization: "This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks and medication interactions. This product is not recommended for use by pregnant or breastfeeding women. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.";

~~(9)~~ (8) The universal warning symbol provided by the department; and

~~(10)~~ (9) A notice with the statement: "This medical cannabidiol is for therapeutic use only. Use of this product by a person other than the patient listed on the label is unlawful and may result in the cancellation of the patient's medical cannabidiol registration card. Return unused medical cannabidiol to a dispensary for disposal."

*b.* Labeling text shall not include any false or misleading statements.

*c.* A package may contain multiple labels if the information required by this rule is not obstructed.

*d.* ~~Labeling text font size shall be no smaller than 6 point~~ A manufacturer shall ensure that directions for use of the product, including recommended and maximum amount by age and weight, if applicable, are included with the product.

ITEM 10. Adopt the following **new** subrule 154.24(4):

**154.24(4)** *Entry into the department's secure sales and inventory tracking system.* Unless otherwise provided in these rules, a manufacturer shall adhere to the following schedule for entering data into the department's secure sales and inventory tracking system.

*a.* A manufacturer shall enter data in real time for data related to:

(1) Inventory of plant material, medical cannabidiol, and waste material;

(2) Transport of plant material, waste material, and laboratory samples; and

(3) Sales of medical cannabidiol to dispensaries.

*b.* A manufacturer shall enter data within five business days for data related to:

(1) Application and use of crop inputs and other solvents and chemicals; and

(2) Other manufacturing and production records not related to inventory of plant material, medical cannabidiol, and waste material.

ITEM 11. Amend subrule 154.25(2) as follows:

**154.25(2)** ~~*Record-keeping and tracking requirements*~~ *Crop inputs and plant batches.*

*a.* All crop inputs used by a manufacturer must be approved by the department prior to the first application of the input. The manufacturer shall use the department's secure sales and inventory tracking system to maintain an electronic record of all crop inputs ~~for at least five years~~. The record shall include the following:

(1) The date of input application;

(2) The name of the employee applying the crop input;

(3) The crop input that was applied;

(4) The plants that received the application;

(5) The amount of crop input that was applied; and

(6) A copy of or electronic link to the safety data sheet for the crop input applied.

*b.* At the time of planting, all plants shall be tracked in a batch process with a unique batch number that shall remain with the batch through final processing into medical cannabidiol.

*c.* A manufacturer shall record any removal of plants from the batch, including the reason for removal, on a record maintained at the manufacturing facility for at least five years.

*d.* Each batch or part of a batch of cannabis plants that contributes to a lot of medical cannabidiol shall be recorded in the department's secure sales and inventory tracking system or other manifest system.

ITEM 12. Amend paragraph **154.26(3)"b"** as follows:

*b.* Conduct sampling and testing of ~~all~~ plant material and medical cannabidiol lots using acceptance criteria that are protective of patient health. The sampling and testing results shall be approved by the department and laboratory personnel and shall ensure that lots of medical cannabidiol meet allowable health risk limits for contaminants. Testing of plant material and lots shall occur as ~~follows:~~ described in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1).

~~(1) At a minimum, testing of lots for cannabinoid potency and all microbiological impurities except microbiological toxins shall occur after packaging but before transport or sale to a dispensary;~~

~~(2) At a minimum, testing of lots for residual solvents and processing chemicals, pesticides, and metals shall occur at the process lot stage. A packaged product that contains medical cannabidiol solely from process lots that passed laboratory testing for residual solvents and processing chemicals, pesticides, and metals does not need to be retested for these analytes provided that solvents and processing chemicals are not used during the processing into the packaged product;~~

~~(3) Testing of lots for residual solvents and processing chemicals shall also occur after packaging but before transport or sale to a dispensary if solvents or processing chemicals are used in the production process after the testing of the process lot has occurred;~~

ITEM 13. Amend paragraph **154.30(1)"j"** as follows:

*j.* Failure of a manufacturer's business owner or investors to have a satisfactory result in a background investigation or national criminal history background check conducted by the department of public safety and as determined by the department.

ITEM 14. Adopt the following **new** subrule 154.40(7):

**154.40(7)** *Recall of medical cannabidiol products.* The department may require a dispensary to recall medical cannabidiol from the dispensary facility and patients when there is potential for serious health consequences from use of the products as determined by the department. Situations that may require a recall include but are not limited to:

*a.* The distribution, sale, or use of the medical cannabidiol creates or poses an immediate and serious threat to human life or health.

*b.* Other procedures available to the department to prevent or remedy a situation would result in an unreasonable delay that may place the health of patients at risk.

ITEM 15. Adopt the following **new** paragraph **154.41(3)"c"**:

*c.* An applicant or licensed dispensary shall respond within 30 days to a request from the department or the department of public safety for more information to complete a background investigation and national criminal history background check on an owner, investor, or employee.

ITEM 16. Amend subparagraph **154.46(2)"a"(4)** as follows:

(4) Issue a label that contains the following information:

1. The medical cannabidiol tracking number; and
2. The ~~date and time the medication is being dispensed~~ patient's registry identification number;
3. ~~The name and address of the dispensary;~~
4. ~~The patient's registry identification number, name, and date of birth;~~
5. ~~The patient's address; and~~
6. ~~Any specific instructions for use based upon manufacturer or departmental guidelines. Labeling text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.~~

ITEM 17. Adopt the following **new** subparagraph **154.46(2)"a"(5)**:

(5) Ensure the following information, which may be printed on a secondary label or package insert, is issued with dispensed medical cannabidiol:

1. The patient's name;
2. The date and time the medical cannabidiol is dispensed;
3. The name and address of the dispensary;
4. Any specific instructions for use based upon manufacturer guidelines or department rules. Labeling text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

ITEM 18. Amend subparagraph **154.46(3)"a"(4)** as follows:

(4) Issue a label that contains the following information:

1. The medical cannabidiol tracking number; and
2. The ~~date and time the medication is being dispensed~~ patient's registry identification number;
3. ~~The name and address of the dispensary;~~
4. ~~The patient's registry identification number, name, and date of birth;~~
5. ~~The primary caregiver's registry identification number, name, and date of birth;~~
6. ~~The patient's address; and~~
7. ~~Any specific instructions for use based upon manufacturer or departmental guidelines. Labeling text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.~~

ITEM 19. Adopt the following **new** subparagraph **154.46(3)"a"(5)**:

(5) Ensure the following information, which may be printed on a secondary label or package insert, is issued with dispensed medical cannabidiol:

1. The patient's name;
2. The primary caregiver's name;
3. The date and time the medical cannabidiol is dispensed;
4. The name and address of the dispensary;
5. Any specific instructions for use based upon manufacturer guidelines or department rules. Labeling text shall not include any false, misleading, or unsubstantiated statements regarding health or physical benefits to the patient.

ITEM 20. Amend paragraph **154.48(2)"a"** as follows:

*a.* A dispensary shall accept at no charge unused, expired, or unwanted medical cannabidiol from any patient or primary caregiver. A dispensary shall provide all returned medical cannabidiol to the manufacturer for disposal.

ITEM 21. Amend subrule 154.72(1) as follows:

**154.72(1)** *Cannabinoids.*

*a.* For each unique lot of medical cannabidiol, and if asked to do so by a requester for other medical cannabis goods, a laboratory shall, at minimum, test for and report measurements for the following cannabinoid analytes:

(1) THC;

(2) THCA;

(3) CBD; and

(4) CBDA~~;~~.

~~(5) CBG; and~~

~~(6) CBN.~~

*b.* A laboratory shall report that the primary sample passed or failed THC potency testing ~~if the detected concentration of THC does not exceed 3 percent by weight in milligrams per milliliter (mg/ml) for liquids and milligrams per gram (mg/g) for solids and if the detected concentration of THC does not vary from the manufacturer's labeled concentration by more than 15 percent by weight in mg/ml for liquids and mg/g for solids~~ according to guidance in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1). ~~Thus, a solid product labeled as containing a concentration of THC of 10 mg/g shall have a detected concentration of THC that is no more than 11.50 mg/g and no less than 8.50 mg/g.~~

~~*c.* A laboratory shall report that the primary sample failed THC potency testing if the detected concentration of THC exceeds 3 percent by weight in mg/ml for liquids and mg/g for solids or if the detected concentration of THC varies from the labeled concentration of THC by more than 15 percent by weight in mg/ml for liquids and mg/g for solids.~~

~~*d.*~~ *c.* A laboratory shall report that the primary sample passed or failed CBD potency testing ~~if the detected concentration of CBD does not vary from the manufacturer's labeled concentration by more than 15 percent by weight in mg/ml for liquids and mg/g for solids~~ according to guidance in the laboratory testing requirements and acceptance criteria document described in subrule 154.69(1). ~~Thus, a solid product labeled as containing a concentration of CBD of 10 mg/g shall have a detected concentration of CBD that is no more than 11.50 mg/g and no less than 8.50 mg/g.~~

~~*e.* A laboratory shall report that the primary sample failed potency testing if the detected concentration of CBD varies from the labeled concentration of CBD by more than 15 percent by weight in mg/ml for liquids and mg/g for solids.~~

~~*f.*~~ *d.* For each cannabinoid analyte test, a laboratory shall issue a certificate of analysis that contains the following:

(1) Concentrations of cannabinoid analytes in mg/ml for liquids and mg/g for solids, or other measures approved by the department.

(2) Whether the primary sample passed or failed the test in accordance with ~~paragraphs 154.72(1)*"b"* and 154.72(1)*"c."*~~ paragraph 154.72(1)*"b."*

~~*g.*~~ *e.* The laboratory may test for and provide test results for additional cannabinoid analytes if asked to do so by a requester.